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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/695,807	10/23/2000	Gregory R. Mundy	432722002623	3395

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EXAMINER

GITOMER, RALPH J

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 03/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/695,807

Applicant(s)

Mundy et al.

Examiner

Ralph Gitomer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 15, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above, claim(s) 25-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 12
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6 6) ☒ Other: Notice to Comply

The amendment, petition to correct inventorship and new Declaration received 5/15/2003 have been entered. Claims 1-43 are currently pending in this application, claims 1-24 are considered here. The election in Paper No. 10 is to the species of bone formation which is considered here. Please update the specification regarding related cases.

The abstract must be presented on a separate page. The amended title is acceptable.

This Office Action is made non-final because art is now applied and double patenting issues considered to the extent possible at this time.

In view of the amendments to the claims, the rejections of record under 35 USC 112, first and second paragraph, are hereby withdrawn.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5-7, 19-23 of copending Application No. 09/421,545. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims include limitations directed to the isoprenoid pathway specifically but are directed to the same compounds as is '545.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 48-70 of copending Application No. 09/558,973. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims include limitations directed to the isoprenoid pathway specifically but are directed to the same compounds as is '973.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The submission of about 100 references received at various times is noted, however it would appear the references are directed toward non-analogous art. None appear to be directed to bone growth treated by any of the classes of claimed compounds. The Applicants are invited to particularly point out any references which may be either specifically analogous or definitely pertinent to the claimed invention. Note 24 USPQ2d *Golden Valley Microwave Foods Inc. v. Weaver Popcorn Co. Inc.* where the patent applicant has duty not just to disclose prior art reference but to make disclosure in such way as not to "bury" it within other disclosures of less relevant prior art.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to provide written description for the presently claimed term "peptidyl aldehyde" in claim 18.

This application contains sequence disclosures, for example at page 27 and 39, that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for one or more of the reasons set forth on the attached form "Notice to Comply with Requirements for Patent Applications

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Containing Nucleotide Sequences and/or Amino Acid Sequence Disclosures".

Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 18, 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Tanihara.

Tanihara (JP 6025288), English translation provided, entitled "Novel Peptides with Transforming Growth Factor Beta Activity: Useful for Treating Wounds, Osteoporosis, Rheumatoid Arthritis, etc." teaches in the English abstract, peptidyl aldehydes for treating osteoporosis. Specifically, N-(tert-butoxycarbonyl)-O-benzyl-L-serine is taught for that function. On page 14 of the translation, fluoride may also be administered simultaneously as an anti-resorptive agent.

Claims 1-3, 18, 22 are rejected under 35 U.S.C. 102(a) as being anticipated by Murray.

Murray (Exp Cell Res) entitled "The Ubiquitin Proteasome System and Cellular Proliferation and Regulation in Osteoblastic Cells" teaches in the abstract, MG-132 or lactacystin treats and regulates osteoblasts related to chymotrypsin activity of the proteasome.

All the features of the claims are taught by the above references for the same function as claimed.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103[©] and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Murray in view of each of Spaltenstein, Adams and Adams.

Murray (Exp Cell Res) entitled "The Ubiquitin Proteasome System and Cellular Proliferation and Regulation in Osteoblastic Cells" teaches in the abstract, MG-132 or lactacystin treats and regulates osteoblasts related to chymotrypsin activity of the proteasome.

The claims differ from Murray in that some of the claims read on additional compounds for treating bone.

Spaltenstein (b)(Tetrahedron Let) entitled "Design and Synthesis of Novel Protease Inhibitors" teaches Ile-Ile-Phe-epoxyketones and other analogs. There are compounds disclosed that read on L-isoleucinamide.

Adams (Bioorg Med Chem Lett) entitled "Potent and Selective Inhibitors of the Proteasome: Dipeptidyl Boronic Acids" teaches in the abstract, selective dipeptidyl boronic acid proteasome inhibitors. On page 333 last paragraph, inhibiting the chymotryptic activity of the proteasome complex by various compounds is discussed. Compounds are disclosed that read on L-leucinamide.

Adams (6,083,903 and 6,297,217) entitled "Boronic Ester and Acid Compounds, Synthesis and Uses" teach compounds that are proteasome inhibitors. See the compounds shown in Table 1.

It would have been obvious to one of skill in this art to employ the compounds of Spaltenstein and Adams in the method of Murray because Murray discloses inhibiting chymotrypsin activity of the proteasome to enhance bone formation and to then employ any compound that is known to inhibit chymotrypsin activity of the proteasome would have been expected to also treat bone.

The following prior art pertinent to applicant's disclosure is made of record and not relied upon:

Mundy (6,492,333) teaches treating bone with PSI.

Elofsson (Chem & Bio) teaches epoxyketones.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ralph Gitomer
Primary Examiner
Art Unit 1651

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